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Appendix 3. Consents explanatory information

European Registry: EuroCareCF/European CF Society
Explanatory Information for getting Patient Consent for CF Registry

1. Participating in the European Registry:

The European Registry is collaborating with the CF Foundation of the US to provide a Global Registry for CF. There are two stages for participation in the registry:

a. Getting informed consent for your patients
b. Entering patient demographic data, and optionally, clinical data

1a. Steps to getting informed consents for your patients:

Please email Gita Mehta (g.mehta@dundee.ac.uk) to confirm your participation in the European Registry so you are kept informed as work progresses.

If you have existing consents which satisfy your local laws:

- Compulsory step: If you already have existing consents, please check with your local Data Protection Officer to make sure these forms meet the requirements of the new European Registry or whether you will need new patient consents using the '*Sample Patient Information Sheet*' and '*Sample Patient Consent Form*' attached.
- Compulsory step: If your local Data Protection Officer approves your existing consents, please inform the European Registry Project Manager, Gita Mehta on g.mehta@dundee.ac.uk along with a copy of the consent form. As soon as the legal and ethics experts of EuroCareCF have also approved this consent, you are ready to place your patient data in the European registry [step (1b) below].

If you do not have existing consents, or you need new patient consents:

- Compulsory step: Please check this Explanatory Information sheet, the accompanying '*Sample Patient Information Sheet*' and '*Sample Patient Consent Form*' with your local Data Protection Officer to make sure these forms meet the requirements of your local legal and ethics laws.
- For more information for your local laws, please consult http://www.privireal.org/
- If you would like any further information, please email the European Registry Project Manager, Gita Mehta on g.mehta@dundee.ac.uk
- Compulsory step: If any changes are required for your country to comply with these sample forms, please let Gita know on the above email.
- Compulsory step: Please get the '*Sample Patient Information Sheet*' and '*Sample Patient Consent Form*' translated if necessary, before getting your patients to sign
- Participation as a CF center where there is no national registry. While it is obviously far better for a country's national registry to be part of the European Registry, it is possible for a single CF center to join the European Registry where it is not possible for the national registry to participate for any reason. If you fall into this category, please let Gita know as special arrangements may apply.
- Compulsory step: Patients can only be entered into the registry once you have received their signed, informed consent to do so.
- Compulsory Step: Please store all the consent forms that your patients have signed safely in your local hospital.

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1b. Entering data into the registry

Countries with existing patient demographic data can either enter this directly into the registry themselves, or this can be entered on their behalf by a trusted third party. Countries who do not currently have patient demographic data should collect these on paper forms prior to this being entered into the registry. Please contact Gita when you are ready to start collecting demographic data.

Countries who wish to do so may also enter clinical data into the registry, and several countries have expressed a wish to use the registry to monitor the progress of their patients in this way. It is the intention that eventually all countries in Europe will use this registry, along with CF centers in the US. Thus the global registry will have a crucial role to play in the treatment of patients with CF.

2. Background to the requirement for getting consents:

- The '*Sample Patient Information Sheet*' and '*Sample Patient Consent Form*' have been checked with the UK Data Protection Office and the legal and ethical experts of EuroCareCF
- They have been written to reflect the design and procedures of the proposed European registry and allow patients to be identified by their hospital teams, but anonymous at a European level.
- Some countries have existing registries (and hence patient consents), others do not
- The '*Sample Patient Information Sheet*' and '*Sample Patient Consent Form*' are to be circulated to those with no consents or those that may require new consents
- EuroCareCF requirements are:
  - Compliance with EC and local laws (to be done by each country locally)
  - Approval by EuroCareCF legal and ethics experts (done for sample forms, required for all others)
  - Patients to be fully anonymous (done via design of registry software)
  - Anonymous data to be released for commercial or research purposes (after approval by ECFS Steering Committee)
    - only if authorised by consents
    - only after ethical approval
    - only if direct treatment benefits result
- Clinical requirements are that patients should be known to their own care teams so that they are provided with the optimum treatment (done by design of registry software)

3. System design and procedures relevant to patient consents:

- Very secure, web-based software
- A two-tier software model. Patients will be identifiable only by their local hospital teams or a trusted third party (data processor). An extraction routine will exclude information that could allow patients to be identified such as their name, country & hospital code, etc. This extracted data will from the European registry.
- For countries with existing registries, data will be mapped directly into the EU registry but again strict controls will allow only anonymous data to be available at a European level.
- Access to the European data for research etc. will be by application to a registry steering committee of the European CF Society (ECFS)
- The intention is to use the software of the American CF registry and share outcome data with them to improve treatment and carry out research. This will be at the level of anonymous European data.
- To further guarantee anonymity, each hospital will be allocated an 'EU-centre' code rather than a country & hospital code. Thus for countries with only one hospital, or small hospitals, where it might have been possible to identify patients from a combination of factors, this will be difficult as only the hospital would know its own 'EU-centre' code. I understand this model has been used for CF DNA diagnostics EQA scheme organised by the Center for Medical Genetics in Leuven since 1996 (Prof. Dr. Els Dequeker — els.dequeker@med.kuleuven.ac.be) — www.cfnetwork.be/www.eurogentest.org.

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